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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,296

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Manuela Guglielmo

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EXAMINER

ROGERS, JUNE MARIE

ART UNIT

PAPER NUMBER

4173

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,296	Applicant(s) GUGLIELMO ET AL.	
	Examiner JUNE M. ROGERS	Art Unit 4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

Applicant's claim of priority to Swiss Application 01258/03 filed July 18, 2003 is acknowledged. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Status of Claims

Claims 1-7 are under consideration in this application.

Claim Objections

Claims 3, 4, and 7 are objected to because of the following informalities: incorrect spelling of panthenol (spelled pantenol in Applicant's application). Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is

Art Unit: 1614

considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim a recites the broad recitation two amino acids, and the claim also recites hydroxyproline and aspartic acid which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's use of both "preparation" and "composition" in the same claim renders the claims indefinite. It is unclear what comprises the preparation and what comprises the composition or if the "preparation" is the same as the composition. Additionally, it is unclear what the word "its" is referring to

Art Unit: 1614

in the phrase "its composition comprises." Does Applicant mean the preparation comprises or does Applicant mean benzyl nicotinate comprises?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desjonqueres (US Patent No. 6,001,378) in view of Hirama et al. (US Patent No. 4,713,397) and Zaveri (US Patent No. 6,376, 557).

Desjonqueres teaches organosilanol derivatives are useful for improving the re-growth of hair and products containing these derivatives act through several mechanisms including:

- a tonic for the vascular walls, which leads to the improvement of the papillary vascularization
- a regulator of cell metabolism which favors the anagenic phase of the pilary cycle
- a stimulant of the synthesis of collagen and of elastin which enables reconstruction of the pilary stem and;

Art Unit: 1614

- a sebo-regulator, which leads to the decrease in the excess of sebum (col. 2, lines 35-50).

Desjonqueures teaches methylsilanol aspartate hydroxyprolinate is such a derivative (col. 4, line 17) and that any organosilanol which is soluble in water and therefore active and assimilated can be used a silanol derivative (col. 4, line, 19-21).

Desjonqueres does not teach the composition also comprises benzyl nicotinate, octyl butyrate, glutamine peptides and panthenol.

It is noted that methylsilanol aspartate hydroxyprolinate is a salt and Applicant's claim 4 is directed to a neutral form of said compound; however, it is common in the art to use both neutral and salt forms of active agents. Therefore, Applicant's claim to the neutral form of a compound already disclosed in the prior art is not given patentable weight; in the absence of a showing of criticality.

Hirama et al. teaches compositions comprising skin peripheral vasodilator drugs (such as benzyl nicotinate) are useful in composition for reducing hair fall-out (abstract). Hirma et al. teaches the benzyl nicotinate can be present in the composition within the range of 0.1 to 2% by weight (col. 1, lines 60-62), Hirma et al. demonstrates the formulation of these compositions with water, ethanol (ethyl alcohol), menthol, and perfume (see examples 1-4).

Hirma et al. does not teach the compositions comprising octyl butyrate and glutamine peptides or panthenol.

Zaveri teaches a method for treating alopecia (hair loss) comprising topically applying a composition comprising octyl butyrate and glutamine-containing peptides

(col. 9, claim 2). Zaveri teaches these compositions can contain preservatives (col. 7, line 67) and panthenol (col. 8, line 9).

Accordingly, one of ordinary skill in the art would have a reasonable of success in formulating a composition comprising the ingredients of Applicant claims 1-7 because the prior art discloses these ingredients are useful in composition for combating and/or delaying hair loss. The idea for combining these references flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423,426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Additionally, no patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

It is noted that the prior art does not teach the percent ranges recited in Applicant's claim 4, however, because the presence of all of Applicant's ingredients is taught in the prior art it would be obvious to optimize the ranges. Accordingly, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, Applicant has failed to demonstrate the criticality of the ranges recited in Applicant's claims 4.

Conclusion

No claims allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JUNE M. ROGERS whose telephone number is (571)270-3497. The examiner can normally be reached on M-T 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Juné M. Rogers

/Ardin Marschel/

Application/Control Number: 10/537,296

Page 8

Art Unit: 1614

Supervisory Patent Examiner, Art Unit 1614